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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,513	08/13/2001	Vivian F. Liu	23US	8239

26618 7590 03/25/2004

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/929,513	LIU ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/21/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group II, claims 11-20 in the paper submitted on December 22, 2003 is acknowledged.

2. Claims 1-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the paper submitted on December 22, 2003.

Response to Amendment

3. Applicant's cancellation of claims 1-10 are acknowledged and have been entered.

4. Claims 11-20 are pending.

Specification

5. The disclosure is objected to because of the following informalities: on page 13, pg. 70, Hamster is misspelled as "Hampster"

6. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 11-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps detailing how to configure a signal line to conduct a time-varying voltage therealong, as well as the steps detailing how to configure one or more ground elements to maintain a time-invariant voltage therealong.

10. In claim 11, it is unclear what is required to configure a signal line to conduct a time-varying voltage therealong, rendering the claim indefinite. It is unclear whether the configuration is based on physical properties of the signal line, or if it requires prior treatment of the signal line, or if some other means of preparation is required to configure the signal line. This is also applicable to the limitation requiring the configuration of ground elements to maintain a time-invariant voltage therealong.

11. Claim 12 recites the limitation "said cell" in the second and third lines. There is insufficient antecedent basis for this limitation in the claim. This is also applicable to claims 15, 16, 18, and 19. Currently the limitation "said cell" is interpreted as cellular system.

12. Claim 13 recites the limitation "said substance" in the first line. There is insufficient antecedent basis for this limitation in the claim. It is unclear if said substance is referring to the substance within the cell, or to the test substance. Currently the substance is interpreted to refer to the substance within the cell.

13. The remaining claims are indefinite for depending on an indefinite claim.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 11-13, 16, 17, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Bodner et al [US 6,461,808].

With respect to claim 11, Bodner et al teach a method comprising the steps of coupling an electromagnetic test signal to a sample in which a cellular event is being detected (claim 1), whereby the sample interacts with and modulates the test signal to produce a modulated test signal, detecting the modulated test signal (claim 1), and analyzing the modulated signal to detect the cellular event (claim 2), where the sample is coupled to the signal by a one-port coplanar waveguide transmission line operable to support the propagation of a electromagnetic test signal comprising a signal line configured to conduct a time-varying voltage (claim 7), and one or more ground elements configured to maintain a time-invariant voltage, the one or more ground elements spaced apart from the signal line and located generally within the same plane as the signal line (claim 7), where a detection region is formed between a portion of the signal line and a portion of the one of the one or more ground elements (claim 6), and where the sample is contained in a sample containment structure intersecting the detection region of the one-port coplanar waveguide transmission line (claims 6 and 7), where the sample

containment structure comprises a cavity operable to hold 1 ml or less of sample solution (column 6, lines 40-45, claim 6) within the detection region.

16. With respect to claims 12, 13, 16, and 17, the cellular activity comprises a change in amount of a substance (ions) present in the cell (opening and closing of ion channels) as a result of the presence of a test substance (antiligand) in a medium containing the cell (column 2, lines 49-67 and column 3, lines 13-41, claim 1). Bodner et al define molecular events as including molecular structures (ion channels) and molecular binding events resulting from the binding of a ligand and its antiligand. Although Bodner et al do not specifically teach that the substance is comprised of ions, a person of ordinary skill in the art would understand the opening and closing of ion channels would cause a change in the amount of ions in the cell, and that the test substance would be considered an agonist or antagonist.

17. With respect to claim 20, Bodner et al further teach a step of verifying the method by correlating with a known cellular activity of a known substance (claim 2).

18. Claims 11-14, 16, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Hefti [US 6,368,795].

With respect to claim 11, Hefti teaches a method comprising the steps of coupling an electromagnetic test signal to a sample (cellular and subcellular systems) in which a cellular event is being detected (claim 1), whereby the sample interacts with and modulates the test signal to produce a modulated test signal, detecting the modulated test signal (claim 1), and analyzing the modulated signal to detect the cellular event (claim 8), where the sample is coupled to the signal by a one-port coplanar waveguide transmission

line operable to support the propagation of a electromagnetic test signal comprising a signal line configured to conduct a time-varying voltage (claims 2-7) , and one or more ground elements configured to maintain a time-invariant voltage, the one or more ground elements spaced apart from the signal line and located generally within the same plane as the signal line, where a detection region (molecular binding layer) is formed between a portion of the signal line and a portion of the one of the one or more ground elements(claim 8), and where the sample is contained in a sample containment structure intersecting the detection region of the one-port coplanar waveguide transmission line (claims 1, 6-8), where the sample containment structure comprises a cavity (chamber) operable to hold 1 ml or less of sample solution (column 41, lines 65-67) within the detection region.

19. With respect to claims 12-14, 16, Hefti teaches the presence or absence of a molecular binding event such as binding between a ligand and antiligand, which are defined to include cells, cell membranes, synthetic compounds, nucleic acids and antagonists (claim 8, column 7, line 48 – column 8, line 24, column 51, lines 50-55).

20. With respect to claim 18, Hefti defines samples as including cells taken from any mammal (column 9, lines 59-67).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. Claims 15, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodner et al [US 6,461,808] in view of Zang-Gandor [Zang-Gandor, Improved transfection of CHO cells, 1997, QIAGENnews, 4, 15-18].

Bodner et al teach the use of cellular systems, as discussed above. Bodner et al do not teach the use of CHO wild-type cells. Zang-Gandor, however, teach that CHO SSF cell lines are able to proliferate as suspension cultures in serum- and protein-free mediums, providing many advantages for economical, large-scale cultivation without expensive additives (p.15, pg.2 – p.l6, pg.1). Therefore it would have been obvious to use CHO wild-type cells as suggested by Zang-Gandor in the method of Bodner et al, in order to allow for economical, large scale cultivation without expensive additives.

23. Claims 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hefti et al [US 6,461,808] in view of Zang-Gandor [Zang-Gandor, Improved transfection of CHO cells, 1997, QIAGENnews, 4, 15-18].

Hefti teaches the use of samples comprising cells from mammals, as discussed above. Hefti does not teach the use of CHO wild-type cells. Zang-Gandor, however, teach that CHO SSF cell lines are able to proliferate as suspension cultures in serum- and protein-free mediums, providing many advantages for economical, large-scale cultivation without expensive additives (p.15, pg.2 – p.l6, pg.1). Therefore it would have been obvious to use CHO wild-type cells as suggested by Zang-Gandor in the method of Hefti, in order to allow for economical, large scale cultivation without expensive additives.

Double Patenting

24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

25. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

26. Claims 11-13, 16, 17, and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,461,808. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application has a common assignee with the patent.

With respect to claim 11, Bodner et al teach a method comprising the steps of coupling an electromagnetic test signal to a sample in which a cellular event is being detected (claim 1), whereby the sample interacts with and modulates the test signal to

produce a modulated test signal, detecting the modulated test signal (claim 1), and analyzing the modulated signal to detect the cellular event (claim 2), where the sample is coupled to the signal by a one-port coplanar waveguide transmission line operable to support the propagation of a electromagnetic test signal comprising a signal line configured to conduct a time-varying voltage therealong, and one or more ground elements configured to maintain a time-invariant voltage therealong, the one or more ground elements spaced apart from the signal line and located generally within the same plane as the signal line, where a detection region is formed between a portion of the signal line and a portion of the one of the one or more ground elements, and where the sample is contained in a sample containment structure intersecting the detection region of the one-port coplanar waveguide transmission line (claims 6 and 7), where the sample containment structure comprises a cavity operable to hold 1 ml or less of sample solution (space for a sample plug, which was defined in the specification (column 6, lines 40-45) to have a volume of preferably 1-10 μl) within the detection region.

Therefore, it would have been obvious to a person of ordinary skill in the art that the limitations recited in the claims of Bodner et al encompass those of the instant application, and it would have been obvious for a person of ordinary skill in the art to perform the method recited by applicants using the method recited by Bodner et al.

27. With respect to claims 12, 13, 16, and 17, the cellular activity taught by Bodner is defined to include a change in amount of a substance (ions) present in the cell (opening and closing of ion channels) as a result of the presence of a test substance (antiligand) in a medium containing the cell (column 2, lines 49-67 and column 3, lines 13-41, claim 1). Bodner et al define molecular events as including molecular structures (ion channels) and

molecular binding events resulting from the binding of a ligand and its antiligand. Although Bodner et al do not specifically teach that the substance is comprised of ions, a person of ordinary skill in the art would understand the opening and closing of ion channels would cause a change in the amount of ions in the cell, and that the test substance would be considered an agonist or antagonist.

28. With respect to claim 20, Bodner et al further teach a step of verifying the method by correlating with a known cellular activity of a known substance (claim 2).

29. Claims 15, 18, and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,461,808 in view of Zang-Gandor [Zang-Gandor, Improved transfection of CHO cells, 1997, QIAGENnews, 4, 15-18].

Bodner et al teach the use of cellular systems, as discussed above. Bodner et al do not teach the use of CHO wild-type cells. Zang-Gandor, however, teach that CHO SSF cell lines are able to proliferate as suspension cultures in serum- and protein-free mediums, providing many advantages for economical, large-scale cultivation without expensive additives (p.15, pg.2 – p.l6, pg.1). Therefore it would have been obvious to use CHO wild-type cells as suggested by Zang-Gandor in the method of Bodner et al, in order to allow for economical, large scale cultivation without expensive additives.

30. Claims 11-14, 16, and 18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,368,795. Although the conflicting claims are not identical, they are not patentably

distinct from each other because the application has a common inventor and assignee with the patent.

With respect to claim 11, Hefti teaches a method comprising the steps of coupling an electromagnetic test signal to a sample (cellular and subcellular systems) in which a cellular event is being detected (claim 1), whereby the sample interacts with and modulates the test signal to produce a modulated test signal, detecting the modulated test signal (claim 1), and analyzing the modulated signal to detect the cellular event (claim 8), where the sample is coupled to the signal by a one-port coplanar waveguide transmission line operable to support the propagation of a electromagnetic test signal comprising a signal line configured to conduct a time-varying voltage (claims 2-7) , and one or more ground elements configured to maintain a time-invariant voltage, the one or more ground elements spaced apart from the signal line and located generally within the same plane as the signal line, where a detection region (molecular binding layer) is formed between a portion of the signal line and a portion of the one of the one or more ground elements(claim 8), and where the sample is contained in a sample containment structure intersecting the detection region of the one-port coplanar waveguide transmission line (claims 1, 6-8), where the sample containment structure comprises a cavity (chamber) operable to hold 1 ml or less of sample solution (column 41, lines 65-67) within the detection region.

Therefore, it would have been obvious to a person of ordinary skill in the art that the limitations recited in the claims of Hefti encompass those of the present application, and it would have been obvious for a person of ordinary skill in the art to perform the method recited by applicants using the method recited by Hefti.

31. With respect to claims 12-14, 16, Hefti teaches the presence or absence of a molecular binding event such as binding between a ligand and antiligand, which are defined to include cells, cell membranes, synthetic compounds, nucleic acids and antagonists (claim 8, column 7, line 48 – column 8, line 24, column 51, lines 50-55).

32. With respect to claim 18, Hefti defines samples as including cells taken from any mammal (column 9, lines 59-67).

33. Claims 15 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,368,795 in view of Zang-Gandor [Zang-Gandor, Improved transfection of CHO cells, 1997, QIAGENnews, 4, 15-18].

Hefti teaches the use of samples comprising cells from mammals, as discussed above. Hefti does not teach the use of CHO wild-type cells. Zang-Gandor, however, teach that CHO SSF cell lines are able to proliferate as suspension cultures in serum- and protein-free mediums, providing many advantages for economical, large-scale cultivation without expensive additives (p.15, pg.2 – p.16, pg.1). Therefore it would have been obvious to use CHO wild-type cells as suggested by Zang-Gandor in the method of Hefti, in order to allow for economical, large scale cultivation without expensive additives.

Conclusion

34. No claims are allowed.

35. The following references are also cited as art of interest for teaching method of detecting or monitoring molecular, binding, and cellular events: Hefti [US 6,566,079], Hefti [US 6,485,905], Kucharczyk et al [US 6,626,902], Hochman [US 6,573,063].

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

37. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
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03/22/04